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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/662,918	09/15/2003	Sean B. Carroll	OPHD-08258	2733
23535 7590 08/22/2007 MEDLEN & CARROLL, LLP 101 HOWARD STREET SUITE 350 SAN FRANCISCO, CA 94105			EXAMINER KIM, YUNSOO	
			ART UNIT 1644	PAPER NUMBER
			MAIL DATE 08/22/2007	DELIVERY MODE PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/662,918	<b>Applicant(s)</b> CARROLL ET AL.	
	<b>Examiner</b> Yunsoo Kim	<b>Art Unit</b> 1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 29 May 2007.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1 and 3-14 is/are pending in the application.
- 4a) Of the above claim(s) 14 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,3-13 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

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### DETAILED ACTION

1. Claims 1 and 3-14 are pending.

Newly submitted claim 14 is directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: Newly submitted claim 14 is drawn to an orally administrable solution comprising an avian antibody reactive to *Clostridium perfringens*, and it has not been claimed previously. The avian antibody reactive to *Clostridium perfringens* can be used in a diagnostic procedure that is patentably distinct from the previously claimed therapeutic method. Since, applicant has received an action on the merits for the originally presented invention, the newly submitted claim 14 is withdrawn from the consideration. See 37 CFR.1.142(b).

Therefore, claims 1 and 3-13 are under consideration in the instant application.

2. In view of Applicants' arguments and the declaration of Stafford filed on 5/29/07, the following rejection remains.

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office Action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

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4. Claims 1 and 3-13 are rejected under 35 U.S.C. 103 as being unpatentable over U.S. Pat. No. 4,748,018 (IDS reference, of record), in view of Uemura et al. (Infection and Immunity, 1974, p. 470-471), of record as is evidenced by Merck Manual of Diagnosis and Therapy (17<sup>th</sup> ed., 1999, p. 1176-1185), of record, for the reasons set forth in the office action mailed on 1/25/07.

Newly submitted claims 8-13 are included in this rejection because “consisting essentially of” in the preamble of claim 8 is being interpreted as “comprising” for the examination purpose.

Applicants’ arguments and the declaration by Stafford filed on 5/29/07 have been fully considered but they were not found persuasive.

Applicants traversed the rejection based on that the ‘018 patent requires developing tolerance to the antibody by virtue of having a history of consumption of the antibody and it teaches away from the claimed invention because the oral tolerance is not practiced. Thus, it is not obvious to combine the references.

It is deemed that Applicants differentiate claimed invention from the reference by the requirement of developing the tolerance. However, the ‘018 patent teaches the tolerance is developed by the subsequent administrations of antibody (col. 4, lines 42-45) and the claimed invention is not limited to a subject who is not previously exposed to the antibody or limited to one oral administration of avian antibody to *Clostridium perfringens*.

Moreover, the claimed invention also requires subsequent administration of avian antibody for effective therapy. The specification of the instant application shows different results. Example 2 (p. 25-26, Table 6) consists of one oral administration of avian antibody to *Clostridium* and Example 6 discloses multiple administrations of avian antibody (p. 38-39). The experimental group of example 2 showed the death at 56 hours while the example 6 showed the prolonged protection. Therefore, the claimed invention implicitly requires developing tolerance as well.

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Furthermore, the Uemura reference and Merck manual have been supplied to recite *Clostridium perfringens* being a pathogen causing food poisoning as well as gastric diseases (p. 470, in particular) and the most common *Clostridium* infections are caused by *perfringens*, *tetani* or *difficile* species. Wound infection, diarrhea and toxic shock are symptoms of clostridial infections and those conditions are treated by similar measures such as antitoxin or antibiotic therapy. Therefore, it is obvious to combine the references.

5. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

6. No claims are allowable.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Yunsoo Kim whose telephone number is 571-272-3176. The examiner can normally be reached on M-F,9-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on 571-272-0841. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Yunsoo Kim

Patent Examiner

Technology Center 1600

August 15, 2007

  
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